

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PC 04 246 K	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/EP2004/005993	International filing date (<i>day/month/year</i>) 03.06.2004	Priority date (<i>day/month/year</i>) 07.06.2003
International Patent Classification (IPC) or national classification and IPC B01J2/16, A61 K31/7048		
Applicant GLATT GMBH		

1.	This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of 4 sheets, including this cover sheet.
3.	This report is also accompanied by ANNEXES, comprising: a. <input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of _____ sheets, as follows: <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4.	This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/005993

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-20 _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. 1-20 _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* _____ received by this Authority on _____
- nos.* _____ received by this Authority on _____
- ☒ the drawings:
- sheets 1/1 _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	1-20	YES
	Claims		NO
Inventive step (IS)	Claims	11-14, 16, 18-20	YES
	Claims	1-10, 15, 17	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims		NO
2. Citations and explanations (Rule 70.7)			
<p>The subject matter of claims 1-20 is novel over the prior art (PCT Article 33(2)) in light of the documents cited in the international search report.</p>			
<p>The problem addressed by the present invention appears to be that of providing an alternative process for producing micropellets. However, in light of the prior art the proposed process does not appear to involve an inventive step, since, compared to other granulation methods, spray granulation is a well-known process for preparing compositions of sparingly soluble active substances. Preparation of substances for granulation in the form of solid dispersions of micronized particles is likewise well known. The quantitative ratios shown also fall within the normal ranges for functional adjuvants and active substance. The list of solutizers in claim 4 is not limiting, since it is preceded by the expression "more particularly". The preferred macrolide antibiotics of the present application are explicitly mentioned among sparingly soluble active substances of the prior art (see EP1027887 (D1) paragraphs 18, 20, 23, 43, 45 and 73; WO02/089773 (D2) pages 16-17 and examples C and D). The process claimed in claims 1-10 and the micropellets or</p>			

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

pharmaceutical presentations thereby obtainable claimed in claims 15 and 17 do not appear to involve an inventive step (PCT Article 33(3)) in light of D1 and D2.

The process claimed in claims 11-14 and the products claimed in claims 18-20 involve an inventive step, since the processes so restricted and the products thereby produced are not suggested by the prior art.

Expressions placed between parentheses in a claim can lead to lack of clarity, since it is not possible to discern whether said expressions have a restrictive effect on the subject matter of the claim in respect of novelty (claims 8, 15 and 16; PCT Article 6).